

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

SHARON HANSON and DAVID HANSON,

Plaintiffs,

v.

Civil Action No. 2:13-cv-10653

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Motion for Summary Judgment)

Pending before the court is defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment against Plaintiffs Sharon Hanson and David Hanson [Docket 41]. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to Ms. Hanson's claims for manufacturing defect, under theories of strict liability and negligence; failure to warn, under theories of strict liability and negligence; breach of express warranty; and breach of implied warranty. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Hanson's claims for design defect under theories of strict liability and negligence; and Mr. Hanson's claim for loss of consortium.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are nearly 75,000 cases currently pending, approximately 19,000 of which are in the BSC MDL, MDL 2326.

In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. (See Pretrial Order # 65, *In re: Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, available at <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. The Hansons’ case was selected as a Wave 2 case by the plaintiffs.

Ms. Hanson was surgically implanted with the Pinnacle Pelvic Floor Repair Kit (the “Pinnacle”) and the Solyx SIS System (the “Solyx”) on May 24, 2010. (Short Form Compl. [Docket 1], at 3–4). She received the surgery at a hospital in Watertown, Wisconsin. (*Id.* at 4). As a result of implantation of the Pinnacle and the Solyx, she has allegedly experienced various injuries. She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breach of express and implied warranties; and punitive damages. (*Id.* at 4–5). Mr. Hanson brings a claim for loss of consortium. (*Id.* at 5). In the instant motion, BSC moves for summary judgment on the grounds that the Hansons’ “legal theories are without evidentiary or legal support.” (Mot. [Docket 41], at 1).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R.

Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict in his [or her] favor.” *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. “When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.” *In re Temporomandibular Joint (TMJ) Implants Prods.*

Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as the Hansons did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) (“For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.”). Ms. Hanson received the implantation surgery for the Pinnacle and the Solyx in Wisconsin. Thus, the choice-of-law principles of Wisconsin guide this court’s choice-of-law analysis.

I find that these principles compel application of Wisconsin law. For tort claims, Wisconsin’s choice of law methodology “begins with a presumption that the law of the forum applies unless ‘nonforum contacts are of the greater significance.’” *Assembly Component Sys., Inc. v. Platinum Equity, L.L.C.*, No. 09-CV-778, 2010 WL 2719978, at *6 (E.D. Wis. July 7, 2010) (quoting *Glaeske v. Shaw*, 661 N.W.2d 420, 427 (Wis. App. 2003)). The methodology then “ends with an analysis of five ‘choice influencing factors’: predictability of results, maintenance of

interstate and international order, simplification of the judicial task, advancement of the forum's governmental interests, and application of the better rule of law." *Id.* Here, given the presumption in favor of the law of the forum, and that there is no indication that any of the five factors would weigh against applying Wisconsin law, I find that the tort claims are governed by Wisconsin law.

III. Analysis

BSC argues that it is entitled to summary judgment in this case because the Hansons' claims lack either evidentiary or legal support. Ms. Hanson has agreed not to pursue claims for manufacturing defect and breach of express warranty. (Pls.' Resp. in Opp'n to BSC's Mot. for Summ. J. ("Resp.") [Docket 67], at 1, 16–17). Accordingly, BSC's Motion for Summary Judgment on Ms. Hanson's claims for manufacturing defect, under theories of strict liability and negligence, as well as breach of express warranty is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

A. Strict Liability

Under Wisconsin law, a manufacturer is strictly liable for design defect if the claimant establishes all of the following by a preponderance of the evidence:

- (a) That the product is defective because it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. . . . [;]
- (b) [t]hat the defective condition rendered the product unreasonably dangerous to persons or property[;]
- (c) [t]hat the defective condition existed at the time the product left the control of the manufacturer[;]
- (d) [t]hat the product reached the user or consumer without substantial change in the condition in which it was sold[; and]
- (e) [t]hat the defective condition was a cause of the claimant's damages.

Wis. Stat. § 895.047.

1. Design Defect

"A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the

manufacturer and the omission of the alternative design renders the product not reasonably safe.”
Id.

Here, BSC argues that Ms. Hanson’s claim for strict liability for design defect fails because the Pinnacle and the Solyx were cleared by the FDA pursuant to the 510(k) process. BSC argues this clearance entitles it to a statutory presumption that the products were not defectively designed. *See* Wis. Stat. § 895.047(3)(b) (“Evidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law agency shall create a rebuttable presumption that the product is not defective.”) Critical to Ms. Hanson’s case, however, when assessing the application of a government standards rebuttal, “parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions” because “[t]he 510(k) process is not a safety statute or administrative regulation.” *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755–56 (S.D. W. Va. 2014); *see also Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015) (applying Wisconsin law) (“As an initial matter, 510(k) is not a ‘relevant standard’ here. Section 895.047 concerns whether a defect rendered the product ‘unreasonably dangerous,’ § 895.047(1), and, as the Supreme Court has held, 510(k) compliance does not go to the safety of a product.”). Accordingly, the rebuttable presumption afforded by section 895.047(3)(b) is not applicable to Ms. Hanson’s case.

BSC next argues that Ms. Hanson’s claim for strict liability for design defect fails under the “ingredient defense” because the alleged defective design is an ingredient that is a characteristic of the product itself. In support of this argument, BSC points to *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674 (Wis. 2009). The plaintiff in *Godoy* claimed that white lead carbonate pigment was defectively designed because it contained lead. *Id.* at 684. The

Wisconsin Supreme Court dismissed the claim, finding that lead was a “characteristic ingredient” of white lead carbonate paint. *Id.* The presence of lead could not make the pigment defective because “[r]emoving lead from white lead carbonate pigment would transform it into a different product.” *Id.* BSC contends that like the lead in *Godoy*, polypropylene is an inherent characteristic of polypropylene mesh products, and therefore, the presence of polypropylene cannot make the mesh defective.

As an initial matter, it is not clear to what extent *Godoy* controls today. The court ruled on *Godoy* in 2009, two years before the enactment of Wisconsin’s codified product liability law. *Godoy*, therefore, represents an application of the common law rather than an interpretation of section 895.047. This does not render *Godoy* inapplicable, however, because section 895.047 contains an affirmative defense similar to the one articulated by the *Godoy* court:

The court shall dismiss the claimant’s action under this section if the damage was caused by an *inherent characteristic* of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Wis. Stat. § 895.047(3)(d) (emphasis added). Because section 895.047 does not indicate whether it replaces the common law or merely supplements it, I will interpret it in addition to *Godoy*.

Nonetheless, BSC’s ingredient defense fails. The plaintiff in this case does not argue that the Pinnacle and the Solyx are defective because of the presence of an inherent characteristic essential to its design—*i.e.*, polypropylene mesh. Rather, the plaintiff argues that the “pelvic mesh products” at issue—the Pinnacle and the Solyx—may be defectively designed, at least in part, due to the use of polypropylene, but that they need not be made with polypropylene at all. (Resp. [Docket 67], at 8). The plaintiff’s argument echoes the terminology set forth in the Master Complaint, which broadly defines the Pinnacle and the Solyx each as a “Pelvic Mesh Product” or “Product”—and not more narrowly as polypropylene mesh products. (*See, e.g.*, Master Long Form

Compl. & Jury Demand, MDL No. 2326, ¶ 7). Accordingly, I find that polypropylene is not necessarily an inherent characteristic of pelvic mesh products. For this reason, Ms. Hanson's claim is distinguishable from the plaintiff's claim in *Godoy*. See *Godoy*, 768 N.W.2d at 682 ("The complaint refers to 'white lead carbonate,' 'white lead pigment,' or 'white lead carbonate pigment' dozens of times. The words 'residential paint pigment' do not appear in the complaint."). Therefore, neither section 895.047(3)(d) nor *Godoy*, precludes Ms. Hanson's strict liability for design defect claim.

To the extent that BSC otherwise contends that summary judgment is warranted, I find that genuine disputes of material fact exist with regard to (1) whether the Pinnacle and the Solyx are unreasonably dangerous and (2) whether safer, alternative designs were available. Therefore, BSC's Motion for Summary Judgment on Ms. Hanson's strict liability for design defect claim is **DENIED**.

2. Failure to Warn

Under Wisconsin law, a product is defective for want of adequate instructions or warnings "only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). A plaintiff suing in strict liability must also prove that the inadequate instructions or warnings were "a cause" of the plaintiff's damages. *Id.* § 895.047(1)(e).

BSC asks the court to employ the learned intermediary doctrine in its application of Wisconsin's statute on failure to warn. The learned intermediary doctrine allows a manufacturer "to fulfill its duty to warn about the known dangers arising from use of its products and avoid liability for failure to warn by adequately warning the physician," thus relieving manufacturers of

prescription drugs and medical devices of the duty to warn the patients directly about the product's dangerous propensities. *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009). If the court applied the learned intermediary doctrine in this case, as BSC urges me to do, BSC's liability for failure to warn would depend on whether it adequately warned the implanting physician, Dr. Miller, about the risks associated with the Pinnacle and the Solyx. Whether it directly warned the plaintiff would not matter.

The Wisconsin Supreme Court has not had the opportunity to decide whether to adopt the learned intermediary rule, *see Forst*, 602 F. Supp. 2d at 968, and federal courts applying Wisconsin law are split on the issue. Several federal courts have used the rule without mentioning that the state supreme court has not yet expressly adopted it. *See, e.g., Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963, *amended*, 532 F. Supp. 211 (E.D. Wis. 1981) (recognizing that the learned intermediary rule is a "general rule [of] the courts of this country"). More recent decisions by federal courts, however, reach the opposite conclusion and decline to apply the learned intermediary doctrine under Wisconsin law. *See Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817, at *5 (E.D. Wis. Feb. 26, 2013) ("Wisconsin does not apply the learned intermediary doctrine"); *Forst*, 602 F. Supp. 2d at 968 (declining to adopt the learned intermediary rule "without some indication that the state's highest court would apply the doctrine if given the opportunity to do so" (quotation marks omitted)); *Peters v. AstraZeneca, LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006) (same).

I need not resolve this issue here. Regardless of whether BSC's duty to warn extended to the implanting physician or to the plaintiff directly, the plaintiff has failed to present evidence that an inadequate warning caused her injuries, as is required under Wisconsin products liability law.

See Wis. Stat. § 895.047(1)(e) (requiring a plaintiff to prove that “the defective condition was a cause” of her injuries). Similarly, in a suit for negligence, the plaintiff must show that the defendant’s breach of duty caused her harm. *See Gritzner v. Michael R.*, 611 N.W.2d 906, 912 (Wis. 2000) (stating that plaintiffs claiming negligence must prove “a causal connection between the defendant’s breach of the duty of care and the plaintiff’s injury”).

Assuming the learned intermediary doctrine applies to this case, the plaintiff must show that Dr. Miller would not have prescribed the device but for the inadequate warnings or instructions. *See, e.g., Forst*, 602 F. Supp. 2d at 968 (explaining that if the learned intermediary doctrine applied, there must be evidence that the omitted warning “would have affected [the treating physician’s] prescribing decision”). The plaintiff has pointed to no evidence to suggest this causal relationship. At most, she shows Dr. Miller’s risk/benefit analysis would have been impacted, (Miller Dep. [Docket 67-8], at 90:20–91:2), but such evidence is insufficient. Indeed, it requires a reasonable juror to speculate, based only on mere *possibility*, that Dr. Miller would have altered her decision to prescribe the product simply because she would have *considered* an additional factor in her risk/benefit calculus. *See Menges*, 61 F. Supp. 2d at 830 (“[A] plaintiff must not only show that the manufacturer’s warning was inadequate, but that such inadequacy affected the prescribing physician’s use of the product and thereby injured the plaintiff.”) (applying Wisconsin law).

Alternatively, assuming the learned intermediary doctrine is inapplicable in Wisconsin such that BSC had a duty to warn the plaintiff directly, the plaintiff still has not provided evidence of causation. In fact, despite arguing against the application of the learned intermediary doctrine in her response, Ms. Hanson provides no evidence that she—instead of Dr. Miller—would have rejected implantation had she known of the warning’s alleged insufficiency. (*See* Resp. [Docket

67], at 12). Therefore, BSC's Motion for Summary Judgment on Ms. Hanson's strict liability for failure to warn claim is **GRANTED**.

B. Negligence

Under Wisconsin law, a negligence action requires the proof of four elements: "(1) A duty of care on the part of the defendant; (2) a breach of that duty; (3) a causal connection between the conduct and the injury; and (4) an actual loss or damage as a result of the injury." *Rockweit v. Senecal*, 541 N.W.2d 742, 747 (Wis. 1995). "The duty of any person is the obligation of due care to refrain from any act which will cause foreseeable harm to others even though the nature of that harm and the identity of the harmed person or harmed interest is unknown at the time of the act." *Id.* After it is shown that a duty of care was owed, "the plaintiff is simply required to prove that the defendant failed to exercise ordinary care and the act or omission complained of was the cause, in the legal sense, of the plaintiff's injury." *Greiten v. LaDow*, 235 N.W.2d 677, 685 (Wis. 1975).

Here, Ms. Hanson's negligence claims fall into the same three categories as her strict liability claims: (1) negligent manufacturing, (2) negligent failure to warn, and (3) negligent design. (See Master Long Form Compl. & Jury Demand, MDL No. 2326, ¶¶ 55–59; Short Form Compl. [Docket 1] ¶ 13). BSC has moved for summary judgment on each category. As noted above, Ms. Hanson does not contest summary judgment on her negligent manufacturing claim.

1. Design Defect

Under Wisconsin law, plaintiffs are permitted "to seek recovery from a manufacturer for the defective design of a product under a strict liability theory and/or a negligence theory." *Morden v. Cont'l AG*, 611 N.W.2d 659, 673 (Wis. 2000) (citing *Sharp v. Case Corp.*, 595 N.W.2d 380, 382 (Wis. 1999)). "The proof required in a strict liability claim differs from the quantum of proof in a negligence claim." *Id.* In a negligence action, "it is not necessary to show that the condition of the product reached the level of unreasonable dangerousness." *Id.* On the other hand, "under a

negligence theory, a plaintiff will not prevail by showing only that a product was defective.” *Id.* In addition, the plaintiff must demonstrate that the defendant was at fault. *Id.* Here, I find that there are genuine disputes of material fact with regard to whether BSC breached a duty owed to Ms. Hanson. Therefore, BSC’s Motion for Summary Judgment on Ms. Hanson’s negligent design claim is **DENIED**.

2. Failure to Warn

As discussed above, *see supra* Section III.A.2, Ms. Hanson has failed to present evidence demonstrating that the alleged inadequate warnings proximately caused her injuries. Therefore, BSC’s Motion for Summary Judgment on Ms. Hanson’s negligent failure to warn claim is **GRANTED**.

C. Breach of Implied Warranty

Under Wisconsin law, “it is inappropriate to bring an action for breach of warranty where a tort remedy is sought.” *Austin v. Ford Motor Co.*, 273 N.W.2d 233, 240 (Wis. 1979); *see also Liberty Mut. Fire Ins. Co. v. LG Electronics USA, Inc.*, No. 10-C-520, 2012 WL 5497852, at *5 (E.D. Wis. Nov. 13, 2012) (dismissing breach of implied warranty claim where plaintiff also brought negligence and strict liability claims). This is because a “breach of warranty theory is encumbered with the ancient baggage of contract actions and should not be employed where the recovery is one for tort.” *Austin*, 273 N.W.2d at 240. Therefore, BSC’s Motion for Summary Judgment on Ms. Hanson’s breach of implied warranty claim is **GRANTED**.

D. Loss of Consortium

BSC contends that it is entitled to summary judgment on Mr. Hanson’s loss of consortium claim because loss of consortium is a derivative claim that cannot survive without Ms. Hanson’s claims. While an accurate statement of the law, Mr. Hanson’s loss of consortium claim survives

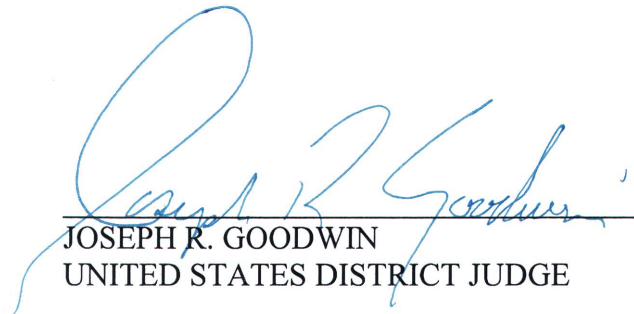
because Ms. Hanson's claims for design defect survive summary judgment. BSC's Motion for Summary Judgment on this claim is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion for Summary Judgment [Docket 41] is **GRANTED IN PART** with respect to Ms. Hanson's claims for manufacturing defect, under theories of strict liability and negligence; failure to warn, under theories of strict liability and negligence; breach of express warranty; and breach of implied warranty. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Hanson's claims for design defect under theories of strict liability and negligence, as well as Mr. Hanson's claim for loss of consortium.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 12, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE